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Office of Regulatory Policy
Food and Drug Administration
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Silver Spring, MD 20993-0002

Marked
JUL 31 2012
DPLA

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,008,765 was filed on April 11, 2012, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, PROGENSA® PCA3 Assay, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.

Since a determination cannot be made whether the patent in question claims the PROGENSA® PCA3 Assay product or a method of manufacturing or use of such a product, which has been asserted to have been subject to regulatory review under the Federal Food, Drug and Cosmetic Act., this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
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